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microgenics

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K011150.

Submitter Information (21 CFR 807.92(a)(1))

Submitter: Microgenics Corporation
46360 Fremont Boulevard
Fremont, CA 94538
phone: (510) 979-5150
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Contact: Sherrie Rinne
Regulatory Specialist

Summary Date: April 12, 2001

Name of Device and Classification (21 CFR 807.92(a)(2))

Name (trade): DRI® DAU Opiate Assay

Name (usual): DJG Opiates enzyme immunoassay

Classification: 21 CFR 862.3100, Class II, DJG (91)

Identification of Legally Marketed Predicate Device(s) (21 CFR 807.92 (a)(3))

The DRI DAU Opiate Assay is substantially equivalent to the existing DRI DAU Opiate Assay (Microgenics Corporation, Fremont, CA), cleared under premarket notification K915180.

DRI DAU Opiate Assay is identical or similar to its predicate in terms of intended use, method principle, device components, risk to the patient, and clinical performance.

Description of Device (21 CFR 807.92 (a)(4))

This opiate assay is a homogeneous enzyme immunoassay using ready-to-use liquid reagents. The assay uses a monoclonal antibody, which can detect opiates in urine. The assay is based on the competition between an enzyme glucose-6-phosphate dehydrogenase (G6PDH) labeled drug and the free drug from the urine sample for a fixed amount of specific antibody binding sites. In the absence of free drug from the sample, the specific antibody binds the drug-labeled G6PDH and the enzyme activity is inhibited. This phenomenon creates a direct relationship between drug concentration in urine and the enzyme activity. The enzyme G6PDH activity is determined spectrophotometrically at 340 nm by measuring its ability to convert nicotinamide adenine dinucleotide (NAD) to NADH.

Intended Use (21 CFR 807.92 (a)(5))

This homogeneous enzyme immunoassay is intended to be used for the qualitative or semiquantitative determination of opiates in human urine with 300ng/mL or 2000ng/mL as a cutoff calibrator.

The assay provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgement should be applied to any drug of abuse test result, particularly when preliminary positive results are used.

Similarities to the Predicate(s) (21 CFR 807.92 (a)(6))

A summary table of the similarities and differences between DRI DAU Opiate Assay and the predicate device follows.

Comparison Table:

DRI DAU Opiate Assay and the existing DRI DAU Opiate Assay

Device Name	Existing DRI DAU Opiate Assay (K915180)	DRI DAU Opiate Assay (new device)
Indications for Use	This homogeneous enzyme immunoassay is intended to be used for the qualitative or semiquantitative determination of opiates in human urine with 300ng/mL or 2000ng/mL as a cutoff calibrator. The assay provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgement should be applied to any drug of abuse test result, particularly when preliminary positive results are used.	This homogeneous enzyme immunoassay is intended to be used for the qualitative or semiquantitative determination of opiates in human urine with 300ng/mL or 2000ng/mL as a cutoff calibrator. The assay provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgement should be applied to any drug of abuse test result, particularly when preliminary positive results are used.

Device Name	Existing DRI DAU Opiate Assay (K915180)	DRI DAU Opiate Assay (new device)
Method Principle	This Opiate assay is a homogeneous enzyme immunoassay using ready-to-use liquid reagents. The assay uses polyclonal antibodies, which can detect opiates in urine. The assay is based on the competition between an enzyme glucose-6-phosphate dehydrogenase (G6PDH) labeled drug and the free drug from the urine sample for a fixed amount of specific antibody binding sites. In the absence of free drug from the sample, the specific antibody binds the drug-labeled G6PDH and the enzyme activity is inhibited. This phenomenon creates a direct relationship between drug concentration in urine and the enzyme activity. The enzyme G6PDH activity is determined spectrophotometrically at 340 nm by measuring its ability to convert nicotinamide adenine dinucleotide (NAD) to NADH.	This Opiate assay is a homogeneous enzyme immunoassay using ready-to-use liquid reagents. The assay uses a monoclonal antibody, which can detect opiates in urine. The assay is based on the competition between an enzyme glucose-6-phosphate dehydrogenase (G6PDH) labeled drug and the free drug from the urine sample for a fixed amount of specific antibody binding sites. In the absence of free drug from the sample, the specific antibody binds the drug-labeled G6PDH and the enzyme activity is inhibited. This phenomenon creates a direct relationship between drug concentration in urine and the enzyme activity. The enzyme G6PDH activity is determined spectrophotometrically at 340 nm by measuring its ability to convert nicotinamide adenine dinucleotide (NAD) to NADH.
Components	- Antibody/Substrate Reagent - Enzyme Conjugate Reagent	- Antibody/Substrate Reagent - Enzyme Conjugate Reagent
Risk to patient	In vitro device for which GC/MS, or other method, must be used to confirm positive results.	In vitro device for which GC/MS, or other method, must be used to confirm positive results.
Clinical Performance	Accuracy: Accuracy against a reference method was 87%. Imprecision: Percent dose CVs across four levels of opiate concentrations were between 0.7% and 5.1%.	Accuracy: Accuracy against a GC/MS reference method was ≥ 96 % (≥89 true positives, ≥74 true negatives, with ≥33 close to the cutoff value). Imprecision: Percent dose CVs across six levels of opiate concentrations were between 1.2% and 4.9%.

Brief Discussion of Nonclinical/Clinical Data (21 CFR 807.92(b)(1, 2))

The DRI DAU Opiate Assay was evaluated via a series of traditional laboratory studies. These studies included the performance characteristics of precision, linearity, accuracy, and specificity.

Precision studies indicated good reproducibility of results at the critical points of the measurement range (distinguishing positive from negative interpretations), as %CVs were below 4.9% for total precision testing, and below 4.0% for within-run precision testing.

The DRI DAU Opiate Assay is linear between 0 ng/mL and 1000 ng/mL or 0 ng/mL and 6000 ng/mL for the 300 ng/mL and 2000 ng/mL cut-offs respectively. The assay also shows good separation in the decision-making ranges between 225 ng/mL and 375 ng/mL or 1500 ng/mL and 2500 ng/mL for the 300 ng/mL and 2000 ng/mL cut-offs respectively.

Accuracy studies showed good performance of the DRI DAU Opiate Assay as compared to the GC/MS reference method. The clinical sensitivity of the assay ranged 99% to 100%. Specificity ranged from 92% to 96%.

Specificity testing demonstrated that the DRI DAU Opiate Assay is not affected by common endogenous substances, variations in urinary pH levels, structurally unrelated pharmaceutical compounds, or potentially cross-reacting compounds.

Performance Data - Conclusions (21 CFR 807.92 (b)(3))

The DRI DAU Opiate Assay has been shown to be substantially equivalent to the predicate device, and safe and effective for its intended use.

CONCLUSIONS

The DRI DAU Opiate Assay was evaluated via a series of traditional laboratory studies. These studies included the performance characteristics of precision, linearity, accuracy, and specificity.

Precision studies indicated good reproducibility of results at the critical points of the measurement range (distinguishing positive from negative interpretations), as %CVs were below 4.9% for total precision testing, and below 4.0% for within-run precision testing.

The DRI DAU Opiate Assay is linear between 0 ng/mL and 1000 ng/mL or 0 ng/mL and 6000 ng/mL for the 300 ng/mL and 2000 ng/mL cut-offs respectively. The assay also shows good separation in the decision-making ranges between 225 ng/mL and 375 ng/mL or 1500 ng/mL and 2500 ng/mL for the 300 ng/mL and 2000 ng/mL cut-offs respectively.

Accuracy studies showed good performance of the DRI DAU Opiate Assay as compared to the GC/MS reference method. The clinical sensitivity of the assay ranged 99% to 100%. Specificity ranged from 92% to 96%.

Specificity testing demonstrated that the DRI DAU Opiate Assay is not affected by common endogenous substances, variations in urinary pH levels, structurally unrelated pharmaceutical compounds, or potentially cross-reacting compounds.

The DRI DAU Opiate Assay has been shown to be substantially equivalent to the predicate device, and safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 2 0 2001

Ms. Sherrie Gene Rinne
Regulatory Specialist
Microgenics Corporation
46360 Fremont Boulevard
Fremont, CA 94538

Re: 510(K) Number: K011150
Trade/Device Name: DRI® DAU Opiate Assay
Regulation Number: 862.3650
Regulatory Class: II
Product Code: DJG
Dated: April 12, 2001
Received: April 16, 2001

Dear Ms. Rinne:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

STATEMENT OF INTENDED USE

510(K) Number (if known): K011150

Device Name: DRI® DAU Opiate Assay

Indications for Use:
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Fred Lacy

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K011150

(PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE AS NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over –the-Counter Use ___
(Per 21 CFR 801.109)